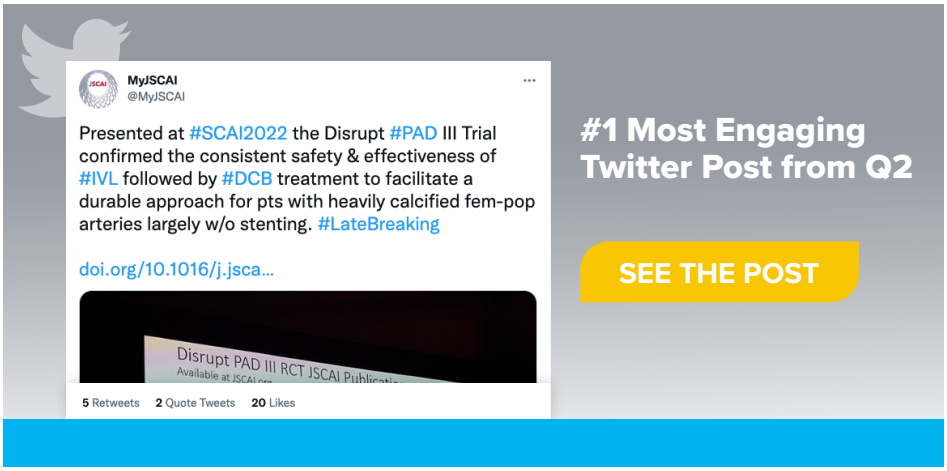
SHOCKWAVE | IVL PREDICTABLY SAFE | DISTINCTLY INTUITIVE | CONSISTENTLY EFFECTIVE

PulsePoint

Shockwave Quarterly Newsletter to Keep Your Finger on the Pulse of IVL News, Trends, & Evidence

Q2'22: Back in Action!

It's been a long two years, but we are thrilled to finally be back in-person at conferences, sharing data and engaging physicians face-to-face again! At SCAI 2022, we announced the long-term results of the randomized Disrupt PAD III Study which demonstrated that peripheral IVL maintained superiority to angioplasty in calcified disease at two years. An expert female panel also presented coronary IVL outcomes in men vs. women at SCAI, demonstrating why IVL may potentially be considered a first-line therapy for calcium modification in female patients. In addition to a busy conference season, Shockwave M^{5+} officially joined physicians' calcium modification toolkit with its exciting new features: 2x faster pulsing, an extended working length and expanded size matrix. Read the PulsePoint newsletter for more information on the data releases, Shockwave M^{5+}, and more!



NEW IVL PUBLICATIONS

Journal of Endovascular Therapy

Intravascular Lithotripsy and Drug-Coated Balloon Angioplasty for Severely Calcified Femoropopliteal Arterial Disease

Dr. Stavroulakis

Read More >

JSCAI

Intravascular Lithotripsy for Peripheral Artery Calcification: Mid-term Outcomes From the Randomized Disrupt PAD III Trial

Dr. Gray and Dr. Parikh

Read More >

JSCAI

Intravascular Lithotripsy vs Atherectomy in the Treatment of Calcified Common Femoral Artery Disease

Dr. Baig, et al.

Read More >

Top 3 Catalyst Posts from Q2

1

2

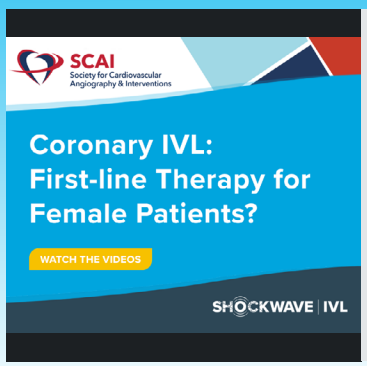
3

PHYSICIAN PERSPECTIVES ON IVL

Change Compliance, Change the Game in EVAR and TEVAR

In this three-episode tutorial series, Dr. Stefano Fazzini and Dr. Michel Bosiers provide an overview on how IVL removes the barriers of calcified hostile access and expands treatment boundaries in EVAR and TEVAR procedures.

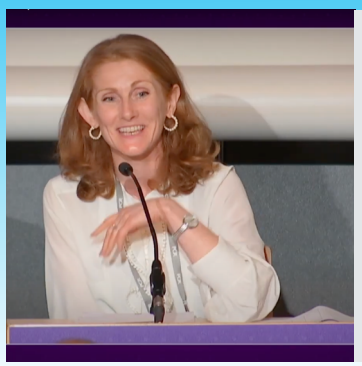
Read More >



Coronary IVL: First-line Therapy for Female Patients?

The blog outlines the clinical evidence presented at SCAI 2022 where Coronary IVL demonstrated sustained long term clinical outcomes and excellent safety in both women and men suggesting potential first-line use of Coronary IVL for plaque modification in female patients with calcified lesions.

Read More >



EuroPCR 2022 Symposium - Conquer Calcium with Shockwave IVL: Cases & Clinical Data

In the sponsored symposium at EuroPCR 2022, Dr. Ribichini, Dr. Neylon, and Dr. Amabile discussed Shockwave IVL usage in different calcium morphologies and its great outcomes in female patients. In addition, Drs. Di Mario, Spratt, and Gonzalo shared the latest clinical evidence and relevant case examples.

Watch Now >

SHOCKWAVE IN THE NEWS

Shockwave IVL Maintains Superiority to Angioplasty in Calcified Peripheral Disease at Two Years

Read More >

Shockwave IVL Coronary Studies Demonstrate Excellent PCI Outcomes in Both Women and Men at One Year

Read More >

Shockwave Sponsors Calcium-focused SCAI Early Career Research Grant

Read More >

FEATURED VIDEO

Watch Dr. Bill Gray and Dr. Sahil Parikh discuss the significance of the PAD III RCT 1 & 2yr Results

Watch the Video >

UPCOMING NEWS

AMP
The Amputation Prevention Symposium

AMP 2022

AUGUST 17-20

Register Now >

TCT 2022

SEPTEMBER 16-19

Register Now >

Important Safety Information

CORONARY ISI:

Rx only

Indications for Use—The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C² Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting.

Contraindications—The Shockwave C² Coronary IVL System is contraindicated for the following: This device is not intended for stent delivery. This device is not intended for use in carotid or cerebrovascular arteries.

Warnings— Use the IVL Generator in accordance with recommended settings as stated in the Operator's Manual. The risk of a dissection or perforation is increased in severely calcified lesions undergoing percutaneous treatment, including IVL. Appropriate provisional interventions should be readily available. Balloon loss of pressure was associated with a numerical increase in dissection which was not statistically significant and was not associated with MACE. Analysis indicates calcium length is a predictor of dissection and balloon loss of pressure. IVL generates mechanical pulses which may cause atrial or ventricular capture in bradycardic patients. In patients with implantable pacemakers and defibrillators, the asynchronous capture may interact with the sensing capabilities. Monitoring of the electrocardiographic rhythm and continuous arterial pressure during IVL treatment is required. In the event of clinically significant hemodynamic effects, temporarily cease delivery of IVL therapy.

Precautions— Only to be used by physicians trained in angiography and intravascular coronary procedures. Use only the recommended balloon inflation medium. Hydrophilic coating to be wet only with normal saline or water and care must be taken with sharp objects to avoid damage to the hydrophilic coating. Appropriate anticoagulant therapy should be administered by the physician. Precaution should be taken when treating patients with previous stenting within 5mm of target lesion.

Potential adverse effects consistent with standard based cardiac interventions include– Abrupt vessel closure – Allergic reaction to contrast medium, anticoagulant and/or antithrombotic therapy-Aneurysm-Arrhythmia-Arteriovenous fistula-Bleeding complications-Cardiac tamponade or pericardial effusion-Cardiopulmonary arrest-Cerebrovascular accident (CVA)-Coronary artery/vessel occlusion, perforation, rupture or dissection-Coronary artery spasm-Death-Emboli (air, tissue, thrombus or atherosclerotic emboli)-Emergency or non-emergency coronary artery bypass surgery-Emergency or non-emergency percutaneous coronary intervention-Entry site complications-Fracture of the guide wire or failure/malfunction of any component of the device that may or may not lead to device embolism, dissection, serious injury or surgical intervention-Hematoma at the vascular access site(s)-Hemorrhage-Hypertension/Hypotension-Infection/sepsis/fever-Myocardial Infarction-Myocardial Ischemia or unstable angina-Pain-Peripheral Ischemia-Pseudoaneurysm-Renal failure/insufficiency-Restenosis of the treated coronary artery leading to revascularization-Shock/pulmonary edema-Slow flow, no reflow, or abrupt closure of coronary artery-Stroke-Thrombus-Vessel closure, abrupt-Vessel injury requiring surgical repair-Vessel dissection, perforation, rupture, or spasm.

Risks identified as related to the device and its use: Allergic/immunologic reaction to the catheter material(s) or coating-Device malfunction, failure, or balloon loss of pressure leading to device embolism, dissection, serious injury or surgical intervention-Atrial or ventricular extrasystole-Atrial or ventricular capture.

Prior to use, please reference the Instructions for Use for more information on warnings, precautions and adverse events.
https://shockwavemedical.com/IFU

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave C² instructions for use containing important safety information.

PERIPHERAL ISI:

In the United States: Rx only.

Indications for Use —The Shockwave Medical Intravascular Lithotripsy (IVL) System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.

Contraindications — Do not use if unable to pass 0.014 guidewire across the lesion—Not intended for treatment of in-stent restenosis or in coronary, carotid, or cerebrovascular arteries.

Warnings — Only to be used by physicians who are familiar with interventional vascular procedures—Physicians must be trained prior to use of the device—Use the generator in accordance with recommended settings asstated in the Operator's Manual.

Precautions — Use only the recommended balloon inflation medium—Appropriate anticoagulant therapy should be administered by the physician—Decision regarding use of distal protection should be made based on physician assessment of treatment lesion morphology.

Adverse effects — Possible adverse effects consistent with standard angioplasty include • Access site complications • Allergy to contrast or blood thinner • Arterial bypass surgery • Bleeding complications • Death • Fracture of guidewire or device • Hypertension/Hypotension • Infection/sepsis • Placement of a stent • renal failure • Shock/pulmonary edema • target vessel stenosis or occlusion • Vascular complications. Risks unique to the device and its use: • Allergy to catheter material(s) • Device malfunction or failure • Excess heat at target site.

Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events.

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave M⁵, Shockwave M⁵⁺, and Shockwave S⁴ instructions for use containing important safety information.

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